JUN 2 8 2001

K011346

EXHIBIT 2

NidaCon International AB
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Contact: Paul V. Holmes ***MSc, PhD, DrMedSc.,*** General Manager

May 1, 2001

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: ***ReadySwim*** ™
   Classification Name/Product Code: Reproductive Media and Supplements (21 CFR 884.6180) Procode: 85 MQL
   Common/Usual Name: Assisted Reproduction Media

2. Equivalent legally marketed devices: **K000621, SperrnRinse** ™ -20/-100

3. Indications for Use (intended use) The product is intended to be used for the preparation of sperm using the swim-up technique of selecting the motile sub-population of spermatozoa from human ejaculates, an adjunct procedure in Assisted Reproduction Technology (ART). There are no changes in the indications for use from the previously cleared product under K000621.

4. Description of the Device: ReadySwim ™ is a balanced salt solution designed for the "swim-up" technique of selecting the motile sub population of spermatazoa from human ejaculates, a standard procedure in Assisted Reproduction Technology (ART).
   - Isotonic salt solution
   - Shelf life of 12 months from production in unopened bottle
   - pH of 7.5 - 8.5 at room temperature
   - Isotonicity of 290 - 300 mOsmlkg water
   - HEPES buffer included
   - Glucose included
   - Low endotoxin levels (< 1.00 EUImL)
   - Aseptically filled and sealed, thereafter terminally sterilised by pasteurisation
   - Packaged in borosilicate glass bottles with silicone stoppers and tamper proof seals
   - Store unopened bottles at ambient temperature, after opening at 4 - 8 °C

5. Safety and Effectiveness, comparison to predicate devices. The results of clinical trials and comparative testing against predicate product indicates that the new device is as safe and effective as the predicate device. The intended use of the product ReadySwim i.e., for selecting motile sperm from human ejaculates using the swim-up technique, indicates that it should never come into contact with the female reproductive tract during normal use. Even if accidental contact did occur, the product should not be irritant or cytotoxic since the recipe is based on the composition of normal human tubal fluid (Quinn et al., 1985). In addition, the recipe includes sodium bicarbonate, HEPES, sodium pyruvate and sodium lactate. Some, or all, of these ingredients are commonly added to salt solutions which have been used for swim-up, for example, Earles Balanced Salt Solution, or are components of the media used to transfer pre-implantation embryos into human patients. Therefore, it is not anticipated that the formulation of ReadySwim would cause irritation or cytotoxicity if the product inadvertently came into contact with body tissues.

6. Conclusion: Based on the similarity of composition, product testing results, and intended use, ReadySwim ^{TM} is substantially equivalent to the predicate device named above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NidaCon International AB
c/o Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015 USA

Re: K011346
Readyswim™
Dated: May 24, 2001
Received: May 25, 2001
Regulatory class: II\
21 CFR 884.6180/Procode: 85 MQL

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

j) Indications for Use

510(k) Number K011346

Device Name: *ReadySwim* ™

Indications for Use: The product is intended to be used for the preparation of sperm using the swim-up technique of selecting the motile sub-population of spermatozoa from human ejaculates, an adjunct procedure in Assisted Reproduction Technology (ART). ReadySwim is intended for use with human semen samples for analysis or for use in the fertilization of oocytes.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011346